

Remarks

Applicants gratefully acknowledge the withdrawal of the previous non-statutory obviousness-type double patenting rejection of claims 1-4. Applicants presume that the previous 35 U.S.C. § 112, second paragraph rejection was overcome since those grounds of rejection were not maintained in the present Office Action. Claims 1-11 are currently pending in this application. Claims 5-11 have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-4 stand rejected under 35 U.S.C. § 112, first paragraph. Applicants' representative thanks the Examiner for discussing the pending claims and the present 35 U.S.C. § 112, first paragraph rejection on April 15, 2004.

Amendments to the Claims

Claims 1-11 have been canceled by this amendment, without waiver or prejudice to filing a divisional application directed to the subject matter of claims 5-11. New claims 12-20 have been added. Original claims 2-4 are being represented as new claims 12-14 with the exception that new claims 12 and 14 have been redrafted in independent form. Applicants submit that new claims 15-20 are supported in the specification, particularly at page 21, line 5 through page 27, line 6 and by original claims 1-4. Applicants further submit that new claims 15-20 are within the scope of original claims 1-4 and therefore are in accord with the previous restriction requirement of the Office Action of April 24, 2003. No new matter has been introduced by this amendment. Applicants have enclosed a fee sheet. If any additional fees are due for this amendment please charge deposit account number 16-1445.

35 U.S.C. § 112, First Paragraph

Claims 1-4 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly being unpatentable for not being enabled. Specifically, the Examiner has alleged that one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine all of the compounds of formula (I) that would be enabled. Although claims 1-4 have been canceled by the present amendment, Applicants are addressing the 35 U.S.C. §112, first paragraph rejection

since new claims 12-14 correspond to original claims 2-4 and new claims 15-20 are within the scope of original claims 1-4. Applicants respectfully traverse the rejection of original claims 2-4, which correspond to present claims 12-14.

Applicants respectfully submit that sufficient guidance and direction has been given for one skilled in the art to practice the present invention and that the present invention is fully enabled. Applicants further submit that one skilled in the art can readily determine the activity of a compound of formula IA against the specified cancers by administering the compound to a patient in need thereof as taught in the specification.

The specification provides a description of compounds of formula IA and particular species within that formula at page 26, line 1 through page 27, line 7. Applicants submit that the compounds of formula IA that are employed in the methods of the present invention are members of a unique class of compounds that are called estrogen agonists/antagonists, and now more commonly referred to as selective estrogen receptor modulators (SERMs). The compounds of formula IA represent a genus of compounds of modest breadth and are taught in the specification, particularly at page 26, lines 1 through 12. Preferred species within formula IA are recited at page 26, line 13 through page 27, line 6 of the specification. Administration of the compounds used in the invention to a patient in need thereof is described in the specification, particularly at page 22, lines 3-10 and page 36, lines 1 through 23. Formulations and dosages for administration of the compounds have been provided in the specification at page 36, line 17 through page 38, line 6 of the specification. Applicants submit that the description of the compounds, routes of administration, dosage forms and pharmaceutical compositions for a compound of formula IA fully enable one skilled in the art to use the compounds of formula IA for the treatment of the specified cancers as presently claimed.

Applicants submit that this description fully enables one of ordinary skill in the art to practice the methods of treatment as claimed without undue experimentation. "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" See *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). Also, the scope of the enablement must only bear a "reasonable correlation" to the scope of the claims. *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970). Applicants have provided sufficient

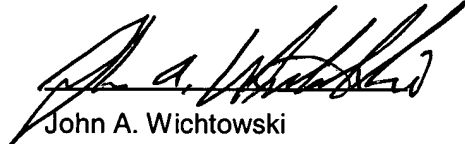
direction and guidance to one skilled in the art to make and use the invention. For the reasons provided hereinabove, applicants submit that original claims 2-4, which correspond to present claims 12-14, are enabled by a full, clear and concise description such that one skilled in the art could make and use the invention without undue experimentation. Furthermore, the scope of the enablement bears a reasonable correlation to the scope of the claims, as amended. For these reasons applicants respectfully request that the Examiner reconsider and withdraw the rejection of original claims 2-4 (now presented as claims 12-14) under 35 U.S.C. § 112, first paragraph.

Enclosed are a Supplemental Information Disclosure Statement and a copy of PTO-FB-A820, which lists an additional reference cited by the applicant(s). A copy of said reference is enclosed as well.

Applicants believe that, in view of the remarks made above, this application is in condition for allowance. Reconsideration of the claims, as amended, and allowance of claims 12-20 is respectfully requested.

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